DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 29 2005

0042 5 OCT -4 P1:48

Sidney M. Wolfe, MD
Peter Lurie, MD, MPH
Frederic Solomon, MD
Mr. Nicholas Stine
Public Citizen
1600 20th Street, N.W.
Washington, DC 20009

Re: Docket No. 2005P-0115/CP1

Dear Doctors Wolfe, Lurie, Solomon, and Mr. Stine:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on March 24, 2005. Your petition requests that the Agency immediately remove from the market pemoline (Cylert manufactured by Abbott Laboratories and all generic versions).

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2005P-0115

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